

ANNEX II

PARTICULAR SAFETY REQUIREMENTS**III. Chemical Properties**

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

2. Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽¹⁾, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁽²⁾ and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽³⁾, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.
3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.
4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:
 - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
 - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
 - (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.That decision may be taken if the following conditions are met:
 - (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
 - (ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

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- (iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:
 - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
 - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or
 - (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and
- (ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.
7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.
8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.
9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.

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10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽⁴⁾.
11. Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylthiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8

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(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenolate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1

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(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

No	Name of the allergenic fragrance	CAS number
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC; and
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V.

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13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
[^{F1} Barium	1 500	375	18 750]
Boron	1 200	300	15 000
[^{F2} Cadmium	1,3	0,3	17]
Chromium (III)	37,5	9,4	460
[^{F3} Chromium (VI)	0,02	0,005	0,053]
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
[^{F4} Lead	2,0	0,5	23]
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) No 681/2013 of 17 July 2013 amending part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys \(Text with EEA relevance\)](#).
- F2** Substituted by [Commission Directive 2012/7/EU of 2 March 2012 amending, for the purpose of adaptation to technical progress, part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council relating to toy safety \(Text with EEA relevance\)](#).
- F3** Substituted by [Commission Directive \(EU\) 2018/725 of 16 May 2018 amending, for the purpose of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chromium VI](#).

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F4 Substituted by Council Directive (EU) 2017/738 of 27 March 2017 amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead (Text with EEA relevance).

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).

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- (1) OJ 196, 16.8.1967, p. 1.
- (2) OJ L 200, 30.7.1999, p. 1.
- (3) OJ L 353, 31.12.2008, p. 1.
- (4) OJ L 262, 27.9.1976, p. 169.